

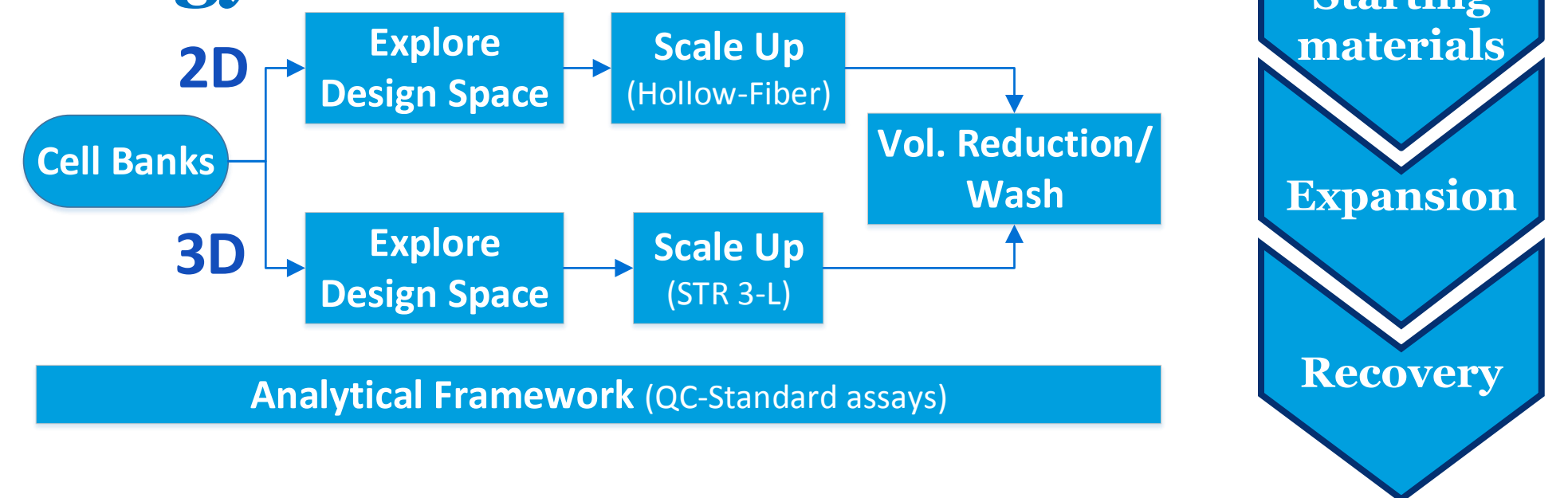
Addressing the challenges of controlled, scalable and affordable expansion of hPSCs for therapeutic use

Terri Gaskell, Jahid Hasan, Daria Popova, Mark Bell, Evangelia Rologi, Marcia F. Mata, Iris A. Valero, Rhys Macown, Matthew Smart, Alexia Toufexi, Mudith Jayawardena, Nicole Nicholas, Ricardo P. Baptista

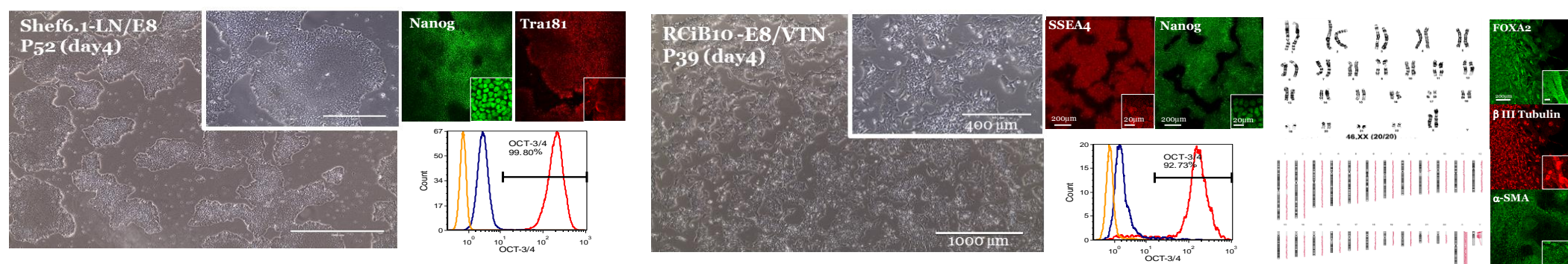
The Cell and Gene Therapy Catapult, 12th floor Guys Hospital, SE1 9RT, London Presenter contact: Terri.Gaskell@ct.catapult.org.uk

Introduction Cost of Goods and process complexity are key challenges for the commercialisation and competitiveness of PSC derived allogeneic therapies. Our Cell Plasticity Platform Programme aimed to design automated processing solutions for the controlled, scalable, and affordable expansion of PSCs in 2D and 3D culture systems. Work is centred around starting materials compliant with industry-standards and development of exemplar processes for scalable expansion with integrated downstream of volume reduction and cell wash.

Strategy



Cell Banks

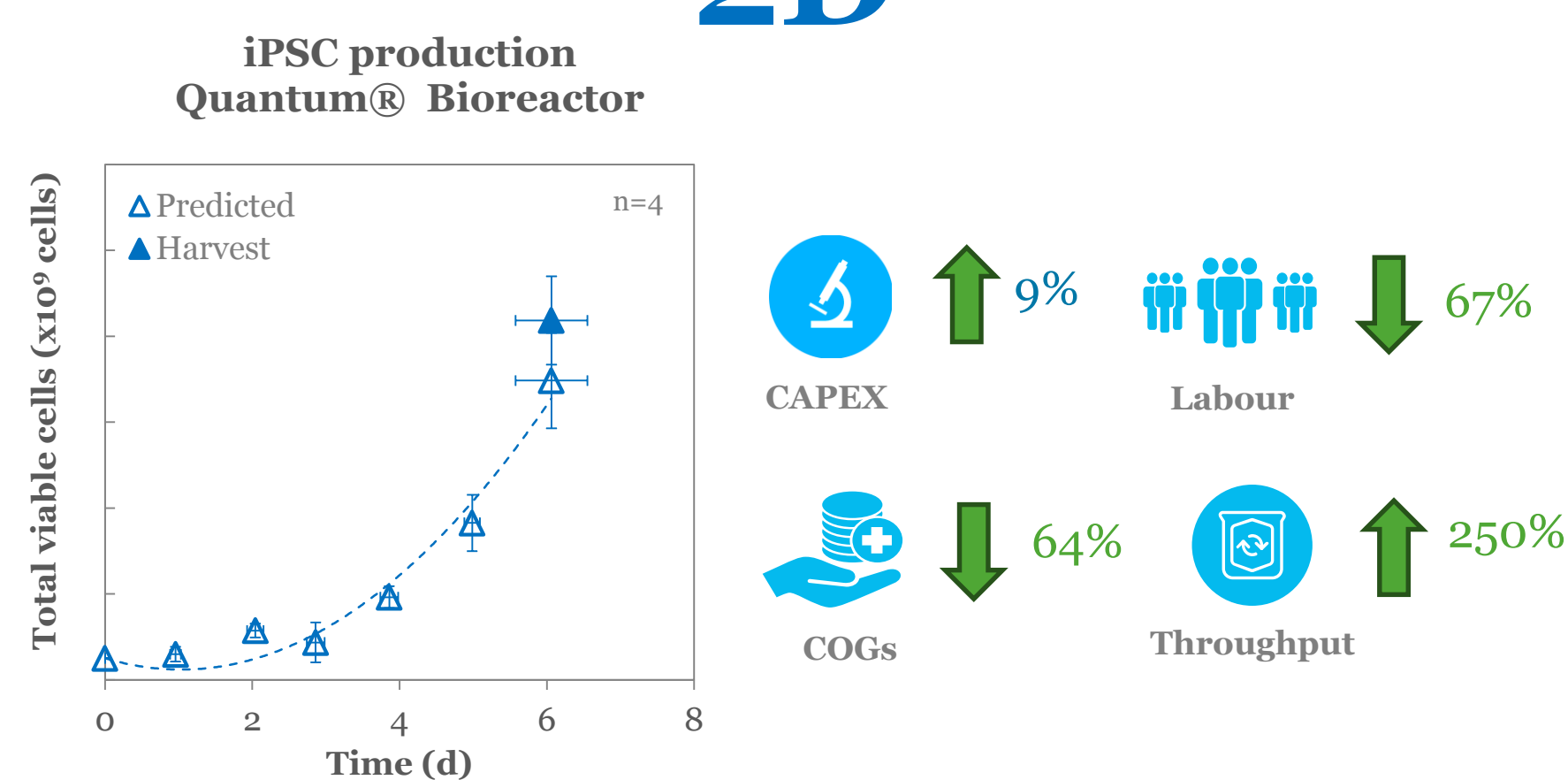


Research-grade banks of exemplar iPSCs (CGT-RCiB10) and ESCs (Shefe.1) adapted to adherent culture in defined reagents have been generated and characterized to industry standards. Stability of iPS cells was tested by monitoring CQA's up to passage P56.

Quality

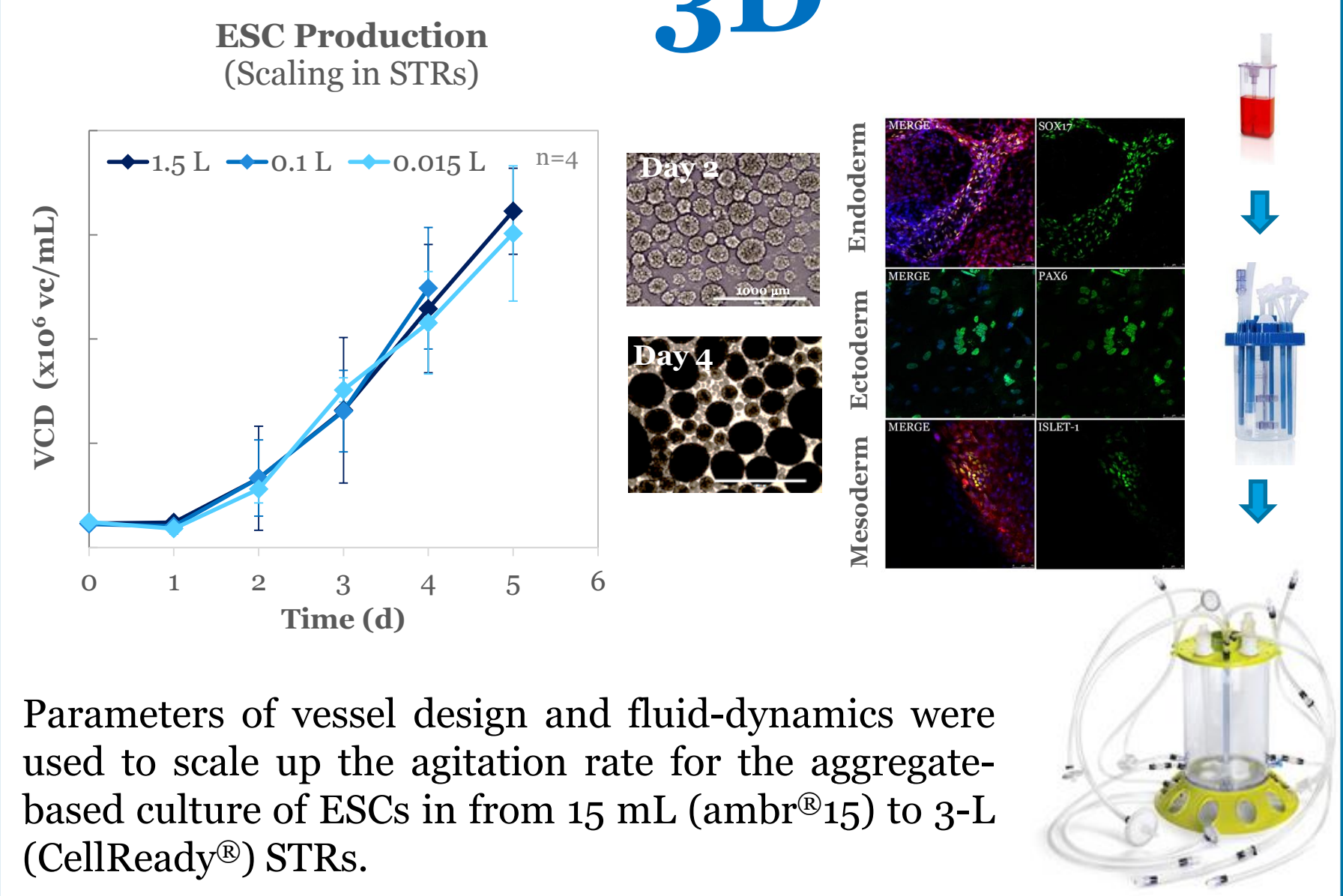
Expansion

2D



By predicting cell numbers based on a metabolite read-out it was possible to automate and up scale the iPSC expansion in the Quantum bioreactor with efficient usage of medium.

3D



Parameters of vessel design and fluid-dynamics were used to scale up the agitation rate for the aggregate-based culture of ESCs in from 15 mL (ambr[®]15) to 3-L (CellReady[®]) STRs.

Automation & Scaling

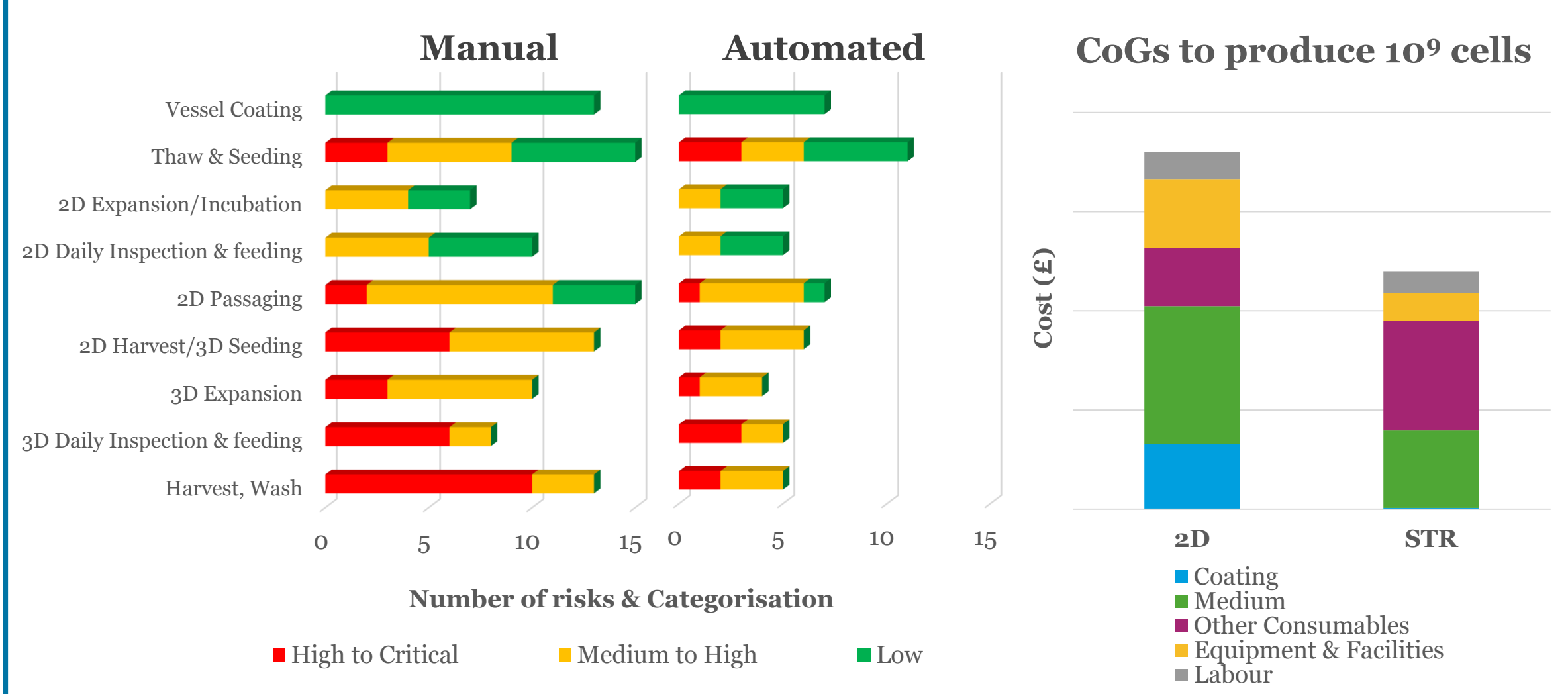
Downstream



Design-of-Experiment methodologies were used to investigate the effect of the process parameters Filter-spin rate and Input cell concentration on the recovery of viable cells after closed and integrated steps of volume reduction (concentration), wash, and formulation of PSCs with the Lovo[®] unit. Similarly, bed establishment and processing flow-rates (Q) were screened for achieving >80% recovery of viable cells with the kSep[®].

Flexibility

Risk & Cost



Summary

- We have established exemplar processes for the scalable and controlled culture of PSCs in single-use hollow-fibre and STR systems.
- We demonstrate technology feasibility to integrate the steps of volume reduction, wash, and formulation for flexible and rapid downstream processing.
- Increasing the level of automation reduced process risks and cost
- Current development strategy is focused on exemplar processes for seamless expansion and differentiation



We work with **Innovate UK**

Cell and Gene Therapy Catapult
12th Floor, Tower Wing, Guy's Hospital, Great Maze Pond, London SE1 9RT
Tel: +44 (0) 20 728 9500 info@ct.catapult.org.uk ct.catapult.org.uk

CATAPULT
Cell and Gene Therapy